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NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD PROGRAM

SECOND ANNUAL REPORT OF THE NATIONAL HEART AND LUNG ADVISORY COUNCIL

DECEMBER 13, 1974

National Institutes of Health
Bethesda, Maryland 20014

National heart, blood vessel, lung, and blood program

SECOND ANNUAL REPORT OF THE NATIONAL HEART AND LUNG ADVISORY COUNCIL

SUBMITTED TO
THE PRESIDENT OF THE UNITED STATES
FOR TRANSMITTAL TO
THE CONGRESS OF THE UNITED STATES
IN ACCORDANCE WITH PUBLIC LAW 92-423

DECEMBER 13, 1974

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
National Institutes of Health
National Heart and Lung Institute
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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NATIONAL HEART AND LUNG INSTITUTE

The President
The White House
Washington, D.C.

December 13, 1974

Dear Mr. President:

The National Heart and Lung Advisory Council is pleased to submit its second annual report to you for transmittal to the Congress. It has been prepared as mandated by Sec. 418 of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 (PL 92-423).

This report covers the activities of the National Heart and Lung Institute for 1974. In preparing it, the Council has reviewed all the grant and contract programs of the Institute. At each of the four meetings this year, the Director of the National Heart and Lung Institute arranged for the Council to spend a significant percentage of its time hearing formal reports from various program areas presented by the Institute staff members who have direct responsibility for them. Thus, over the year, the Council has reviewed all the grant and contract programs of the Division of Heart and Vascular Diseases, the Division of Lung Diseases, and the Division of Blood Diseases and Resources.

As will be detailed in this second annual report, the National Heart and Lung Advisory Council is impressed that the Act of 1972 and the accomplishments of 1974 are having a substantial effect in improving diagnosis, treatment, and prevention of diseases of the heart, blood vessels, lungs, and blood. For example, the following notable advances are described which either have immediate application to patient care or hold much promise: methods for detecting the amount of heart muscle damaged by a heart attack and treatments for limiting such damage, new diagnostic and treatment programs which will decrease infant mortality from hyaline membrane disease, and promising new approaches for treatment of hemophilia and sickle cell anemia.

The Act of 1972 is having a substantial salutary effect even though the monies appropriated to support the National Program of the Institute are much less than authorized by the Act. It is obvious, of course, that without an increase in appropriations, many programs mandated by the Act and planned for in the Institute's National Program have not been fully developed. It seems clear to the Advisory Council that the benefit of the Act reflects the effectiveness of short-term and long-term planning in an institute such as the National Heart and Lung Institute that has the fortunate combination of high quality management and strong research grant and contract programs.

To help assure a continued improvement in diagnosis, treatment, and prevention of diseases covered by the Act, this report presents a number of recommendations as well as some suggestions for legislative action. We, as members of the Council, would be happy to provide any additional information that you or members of the Congress may wish to have.

As members of the Council, we hope that you and the Congress will share with us an enthusiasm for the National Program of the National Heart and Lung Institute and pride in its accomplishments.

Respectfully,

The National Heart and Lung Advisory Council

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I

INTRODUCTION

The National Heart, Blood Vessel, Lung, and Blood Act of 1972 expressed the determination of the President and the Congress to lessen the human suffering and financial burden caused by cardiovascular, pulmonary, and blood diseases, and to improve the utilization of national blood resources. It mandated the development of a plan for a National Program by the National Heart and Lung Institute (NHLI) to implement the Act and carried an authorization for annual appropriations to support the expanded effort. It required that the National Heart and Lung Advisory Council submit an annual report to the President and the Congress on the progress of the Program.

The Council has reviewed the programs of the Institute and proposals for future work. It finds that substantial progress has been made and that research results are being translated rapidly into improved health care. Clearly, under the Act, much has been accomplished. Important information is being obtained, as will be detailed in this report, and it is being applied to improve medical diagnosis and treatment. However, because the appropriations authorized by the Act have not been forthcoming, many things have not been accomplished as planned. For example, the public education programs are less than completely implemented, emergency medical services are not widely available, and only three of the National Research and Demonstration Centers have been established.

Although full implementation of the Act has not been possible, the Council finds that the National Program has made substantial progress in many areas addressed by the Act. Accordingly, the Council recommends that the Act be renewed, and this report will detail the accomplishments that form the basis for this opinion. It will also make recommendations for strengthening the National Program.

In making these recommendations, the Council is keenly aware that the diseases addressed by the National Program are not the only ills that afflict the nation and that, in actuality, many agencies in addition to the NHLI participate in aspects of the Program. Important to its success are those programs of other National Institutes within the National Institutes of Health (NIH): Aging; Allergy and Infectious Diseases; Arthritis, Metabolism, and Digestive Diseases; Child Health and Human Development; Environmental Health Sciences; General Medical Sciences; Neurological Diseases and Stroke; and the National Cancer Institute. Research going on in or supported by these and other parts of the NIH may be of signal importance to certain aspects of the NHLI effort because knowledge gained in one field is often found to be applicable in others.

It is thus essential that the present trend to decrease support to most other Institutes should be reversed. In addition, the Council recognizes that the voluntary health agencies in this country are potent forces in achieving the goals of improved national health through their support of research and their widespread and vigorous public education programs. This Institute will continue its collaboration with the American Heart Association, the American Lung Association, the National Hemophilia Foundation, and other organizations related to its mission.

II

CONCLUSIONS, RECOMMENDATIONS, AND SUGGESTIONS FOR LEGISLATIVE ACTION

In Chapters III and IV of this report, the National Heart and Lung Advisory Council reviews the accomplishments of the National Heart, Blood Vessel, Lung, and Blood Program, cites the urgent requirements of this Program, and discusses ways in which they may be met. The Council has reached the following conclusions and makes specific recommendations and suggestions for legislative action required to advance the National Program.

CONCLUSIONS AND RECOMMENDATIONS

RESEARCH MANPOWER DEVELOPMENT

The Council again emphasizes that continued improvement in national health requires a steady flow of young investigators developing into mature scientists who can continue to provide new knowledge. The uncertainties created by the changes in manpower development programs in the past few years have turned young people away from research careers. The National Research Service Award Act of 1974 has returned some stability to this program but has not solved the problems entirely. To assure the continuation of this vital program in the years to come:

- The Council recommends that a stable policy of manpower development in biomedical research should be established and implemented consistently.

RESEARCH GRANTS AND CONTRACTS

The Council considers that the most significant advances in prevention and treatment of heart, blood vessel, lung, and blood diseases will come from enhanced understanding of the underlying disease processes. This understanding will be provided by innovative, creative, imaginative scientists, because it is these people who can, and will, develop the necessary new information.

- The Council emphasizes, therefore, the urgent need to increase funds for research grants.

In the clinical translation of research results, the contract mechanism has proved useful for evaluation and testing of promising methods for diagnosis and treatment, and for the evaluation of new therapies through large-scale clinical trials.

- The Council recommends that the contract mechanism continue to be used to expand the application of new information but not at the expense of generating additional information through individual research grants.

BLOOD RESOURCES

The Council is concerned that progress has not been more rapid with regard to the best use of blood resources even though the need was clearly recognized in the 1972 Act.

- The Council recommends that a nationwide study be undertaken to determine if needed blood and blood derivatives are being made available to patients in the most effective manner possible and, if not, what problems and remedies can be identified.

CENTERS OF RESEARCH EXCELLENCE

The Council believes that one of the vital forces for the superb biomedical research effort of this country has been the centers of research excellence that have developed in research institutions here.

- To assure the continuance of such excellence over the long term, the Council recommends establishment of Professorial Research Groups and Research Professorships as presented in the Council's initial report of April 1973,[1] as well as in its First Annual Report.[2]

CONSTRUCTION OF RESEARCH FACILITIES

Present physical resources are overcrowded and antiquated in many hospitals and research institutions across the nation.

- To provide the physical resources required for the acquisition of new information so that we may improve diagnosis, prevention, treatment, and public health education, funds for support of construction should be appropriated.

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[1] National Heart, Blood Vessel, Lung and Blood Program. Volume II. Report of the National Heart and Lung Advisory Council. DHEW Publication No. (NIH) 73-516. April 12, 1973.

[2] National Heart, Blood Vessel, Lung, and Blood Program. First Annual Report of the National Heart and Lung Advisory Council. DHEW Publication No. (NIH) 74-503. December 17, 1973.

INTER-COUNCIL COLLABORATION

As knowledge increases, programs for applying it toward improved diagnosis and treatment of all diseases increase in number and complexity. This is true not only for the NHLI but also for all the Institutes. Further, the ability of the NHLI to accomplish the goals of the National Program depends in large measure upon the policies and operational procedures of the NIH as a whole. In establishing goals for the acquisition of new information and in developing programs of clinical application, inter-Institute collaboration is both highly desirable and necessary. Although the Interagency Technical Committee, established by the National Heart, Blood Vessel, Lung, and Blood Act of 1972, serves the purpose of improving collaboration at the staff level, there is no provision for inter-Council collaboration.

- The Council views inter-Council collaboration as an effective means for improving the programming and policies of the National Institutes of Health and recommends that an Inter-Council Advisory Committee be formed. It should be composed of two scientists from each National Advisory Council of the NIH and should be advisory to the Director of the NIH.

STAFFING

The Council concludes that the level of staffing within the NHLI is inadequate for carrying out the expanded programs mandated by the Heart, Blood Vessel, Lung, and Blood Act of 1972. Each of the three categorical Divisions within the Institute has responsibility for new programs. Also, these new programs have greatly increased the responsibilities of the Division of Extramural Affairs. Although fiscal obligations of the Institute have increased 78 percent between FY 1970 and FY 1974, employment has increased only 23 percent.

- Therefore, the Council urges that the staff of the NHLI be increased from its present level of 692 to approximately 800 permanent full-time positions.

NHLI LOCATION

Currently, operations at the NHLI are carried out in three separate locations, two of which are some distance from the NIH campus. Such separation of activities and staff is counterproductive and, as the responsibilities of the Institute increase, the need for close staff collaboration also will increase.

- The Council recommends that the staff of the NHLI be assigned to one location.

BUDGET

The diseases covered by the National Heart, Blood Vessel, Lung, and Blood Act of 1972 are the major causes of death and disability in this country. Thus, the programs of the NHLI are of vital importance to national health and of immediate concern to the public and its elected representatives. Clearly, major decisions concerning these programs should be made in the public arena.

- The Council recommends, therefore, that the present system by which the Congress establishes separate appropriations in the Federal budget for the NHLI should be continued to assure public and congressional access both to planning and review of the Institute's programs.

SUGGESTIONS FOR LEGISLATIVE ACTION

THE NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD ACT OF 1972 (Public Law 92-423)

The National Program to conquer heart, blood vessel, lung, and blood diseases has just begun. Already significant advances have been made.

- The Council urges the Congress to renew the National Heart, Blood Vessel, Lung, and Blood Act of 1972.

In considering the renewal, the Council presents the following specific recommendations:

- To provide the physical resources needed for the acquisition of new information to improve diagnosis, treatment, prevention, and public health education, construction funds should be appropriated, not only for the National Research and Demonstration Centers but also for other research institutions. So that all institutions may compete equally for such funds, the Council urges that the availability of matching funds not be a condition of such awards.

- The Director of the NHLI should be authorized to approve grants and awards up to $35,000, direct costs, as recommended by initial review groups, without Council review. As mandated in the Act of 1972, these grants and awards may not now exceed $35,000 total costs.

- The Council should be authorized to submit its annual report to the President and the Congress simultaneously rather than to the President for transmittal to the Congress as now obtains. This would allow the Congress and the public to have prompt access to the report.

THE NATIONAL RESEARCH SERVICE AWARD ACT OF 1974 (Public Law 93-348)

A stable research manpower development program is essential if progress in heart, blood vessel, lung, and blood diseases is to continue. To provide the necessary biomedical scientists needed:

- The Council urges that the Congress renew the Act for a period sufficient to guarantee stability of research manpower development programs.

In considering the renewal, the Council makes the following specific suggestions:

- Predoctoral as well as postdoctoral programs should be supported.
- The NHLI, and other Institutes of the NIH, should be able to determine manpower needs in areas deemed by the Council and the Institute to be in danger of suffering manpower shortages. To accomplish this goal, the NHLI should have the responsibility for making awards it considers absolutely necessary with up to 25 percent of the funds available for manpower development.
- Although individual fellowships are to be the main source of manpower development, the Institute should also be authorized to support excellent institutional programs in addition to those determined by the National Academy of Sciences to be necessary to meet current manpower needs.

CONFIDENTIALITY—AN IMPORTANT PART OF THE GRANT MECHANISM

The Council recently has reviewed the opinion handed down by the U.S. Court of Appeals for the District of Columbia Circuit Court in the case of Washington Projects, Inc., v. the Department of Health, Education, and Welfare, et al., No. 74-1027. This was an appeal of the District Court judgment ordering disclosure of information sought about 11 projects funded by the National Institute of Mental Health. The Appeals Court has held ". . . that the 11 grant applications . . . , together with any continuation renewals, or supplemental applications incident thereto (either approved or pending), are not exempt from disclosure under the Freedom of Information Act." However, it partly reversed the judgment of the District Court by holding ". . . that site visit reports and summary statements are exempt under Exemption 5."

Although the Council has not had time to study this opinion in the desired detail, it wishes to raise a generic concern. Free access to approved grant applications has several possible disadvantages for the public and for individuals.

In particular, the Council is concerned that this ruling has the potential for giving undue advantage to large, over small, institutions that would allow large research teams to capitalize on the ideas and plans coming from institutions with fewer research scientists and smaller research teams. It could lead to migration of scientists away from smaller institutions and diminish the number of faculty available for both predoctoral and postdoctoral training at those institutions.

- The Council recommends, therefore, that the Congress take appropriate action to clarify the intent of the Freedom of Information Act so that the public investment in the support of biomedical research remains fully protected.

NHLI APPROPRIATIONS

The Council has reviewed the past and current funding of the NHLI programs. As shown in Table 1, appropriations have not kept pace with authorizations under the 1972 Act. Indeed, there is an absolute decrease in the funds available in the FY 1975 budget for the NHLI in addition to a relative decrease due to a failure of appropriations to keep pace with inflation.

- The Council recommends that approximately $494 million, $608 million, $632 million, $642 million, and $695 million be authorized in FY 1976-80.

Table 1. National Heart and Lung Institute Funding for Fiscal Years 1973-75 (Dollars in Millions)

Funding	FY 1973	FY 1974	FY 1975
Authorized by Congress	$400	$460	$520
Previously Recommended by Council	--	422	520
Appropriated	300*	303	324**

*Includes $44 million that was impounded, subsequently released and made available for obligation in FY 1974 and 1975.

**Authority to obligate all of these appropriated funds has not yet been received.

Table 2 presents comparisons of actual obligations in FY 1974, appropriation level for FY 1975, and the Council's recommendations for future support required to advance the National Program. The recommended FY 1976 budget has been adjusted to the realities of current spending levels so that requirements for a strong national program can be met as quickly as possible.

- The Council recommends that the funds indicated in Table 2 for FY 1976-80 be appropriated.

Table 2. National Heart and Lung Advisory Council's Recommended Annual Budget for Fiscal Years 1976-80 (Dollars in Thousands)

Program Activities	FY 1974 (Actual)	FY 1975 (Appropriation)[1]	FY 1976 (Recommended)	FY 1977 (Recommended)	FY 1978 (Recommended)	FY 1979 (Recommended)	FY 1980 (Recommended)
Research Projects and Program Projects	$149,147	$145,000	$195,000	$231,500	$243,100	$255,300	$270,000
Special Projects							
Heart Co-op Drug Study	4,897	886	--	--	--	--	--
SCORs[2]	24,444	36,663	40,000	42,000	45,000	47,500	52,250
Control Programs	1,065	3,000	15,000	31,800	33,700	35,700	39,270
Research Professorships	--	--	5,000	12,000	12,700	13,600	14,960
Professorial Research Groups	--	--	8,000	18,000	19,000	20,000	22,000
National R&D Centers[3]	--	6,405	20,000	48,000	54,000	60,000	66,000
Construction	--	--	60,000	45,000	30,000	--	--
Manpower Development	19,394	20,000	32,000	33,000	34,600	36,300	39,330
Intramural Research	22,348	24,000	25,000	27,500	30,300	33,000	36,000
R&D Contracts[4]	89,534	70,780	76,000	100,000	110,000	120,000	132,000
Research Management & Program Services	15,371	17,396	18,000	19,000	20,000	21,000	23,000
TOTAL	$326,200	$324,130	$494,000	$607,800	$632,400	$642,400	$694,810

[1] Authority to obligate all of these appropriated funds has not yet been received.
[2] Specialized Centers of Research (SCORs).
[3] National Research and Demonstration Centers.
[4] Research and Development Contracts.

III

ACCOMPLISHMENTS AND REQUIREMENTS FOR A SOUND NATIONAL PROGRAM

The National Heart, Blood Vessel, Lung, and Blood Act of 1972 bore witness to the recognition by the President and the Congress that these diseases constitute the greatest threat to our national health and that concerted efforts in research and clinical treatment will bring about substantial improvement. In the National Heart and Lung Advisory Council's initial report,* the following statement appears: "The maturation of many research-proven ideas, methods and technologies, viewed in relation to the increasing health problems of heart, blood vessel, lung and blood diseases, convinces the Council that the next few years could bring significant new discoveries and health benefits for the American people."

In reviewing the Program's accomplishments to date, the requirements that remain, and the requisites for meeting them, the reality of that statement is apparent because advances have been made. They come, however, not from this recently launched, formally coordinated program, but from research that has been going on for many years. Truly, these impressive accomplishments represent "the maturation of many research-proven ideas, methods and technologies." One of the purposes of the Act and the National Program is to hasten the maturation.

For this, its Second Annual Report (1974), the Council has chosen to highlight a few of the accomplishments that represent important advances in the understanding and control of heart, blood vessel, lung, and blood diseases. Some of these show promise of expanding our knowledge and have great potential for improving health; others that have immediate important clinical application are expected to improve the care of afflicted people in a highly significant way in the very near future.

These accomplishments are premier examples of how requirements that are met result in greatly improved medical diagnosis and treatment. They show clearly and repeatedly that research "pays off." From them one gets an idea of the shape of things to come: this nation's effort to combat heart, blood vessel, lung, and blood diseases has arrived at the stage where appropriate emphases can bring improvements that could not have been envisioned even as recently as two decades ago.

*See footnote 1, page 4.

HEART AND BLOOD VESSEL DISEASES

In this country, diseases of the heart and blood vessels are the major causes of premature death and disability. The Council will concentrate on atherosclerosis and hypertension because of their numerical significance and because, in the case of atherosclerosis, new information is urgently needed and, in the case of hypertension, methods of control are now available and lack only large-scale application for nationwide effectiveness.

ATHEROSCLEROSIS

Atherosclerosis continues to be the largest single cause of premature death and disability. It is responsible for heart attack, stroke, aneurysm, peripheral vascular disease, and sudden death. It is a disease of large and medium sized arteries that usually starts in childhood and progresses for decades before it produces symptoms. The disease has at least three components: fibrous tissue overgrowth, the abnormal deposition of fat from the blood, and clotting (thrombosis) in or on the wall of the artery. This combination of events is responsible for the plaques that narrow the artery and progressively limit blood flow to the tissue that the artery supplies. There is often a critical episode--a catastrophe. This is the sudden occlusion of the narrowed vessel by a blood clot, and it is this sudden and complete blockage that is responsible for myocardial infarction and thrombotic stroke. Both can kill--the myocardial infarction because it so upsets the electrical stability of the heart that normal rhythm mechanisms are disordered, or because so much heart muscle is rendered functionless that the pumping capacity fails, and stroke because the vital functions that are controlled by the brain are crippled.

In highly developed societies, atherosclerosis seems to occur almost universally in the course of a long life. There are, however, a number of factors that increase the risk of developing this disease prematurely, such as elevated blood cholesterol, hypertension, cigarette smoking, rapid heart rate, diabetes, physical inactivity, elevated uric acid in the blood, and a family history of the disease. Yet even these do not account for all the premature changes of atherosclerosis that occur in this country; so the search goes on for other factors.

Accomplishments

Until we know how all the major factors responsible for atherosclerosis cause the plaques to develop and then grow, progressively narrowing arteries, there can be no truly effective programs of prevention. The information is not yet available but important progress is being made.

Two examples seem worthy of note. One concerns smooth muscle cells that are normal components of the arterial wall, but their deranged metabolism seems to be an important factor in development of the fibrous component of the atherosclerotic plaque. The other concerns a cell defect in patients with an inherited

form of high blood cholesterol (familial Type II hyperlipoproteinemia) which is consistently associated with premature atherosclerosis.

- It is now possible to grow arterial smooth muscle cells in tissue culture. This ability to grow, outside the body, the cells responsible for the progressively occlusive atherosclerotic plaque, makes available a method for studying their metabolism and how it is modified by the factors that we know promote atherosclerosis.

- A tissue culture study of skin fibroblasts (cells that make fibrous tissue) suggests that the fault in inherited hypercholesterolemia is a deficiency in the binding of certain fat-carrying proteins to the cell membrane. The binding of these cholesterol-carrying proteins apparently is necessary for the normal removal of cholesterol from the bloodstream. Thus, a genetically determined deficiency of binding sites leads to a delay in the removal of cholesterol from the blood and apparently explains the high blood cholesterol level in Type II hypercholesterolemia. These research results are expected to provide new approaches to the understanding and control of this type of premature atherosclerosis.

Requirements

In an area where as much fundamental information is lacking as it is in atherosclerosis, many requirements remain. The Institute is making excellent progress in identifying and meeting them. It is obvious, however, that information not now available will be needed and it can only be obtained from a variety of research approaches. The Council believes the following to be necessary:

- Identification of the basic cellular and metabolic mechanisms in the development of atherosclerotic plaques

- A systematic approach to the investigation of all the known risk factors involved in the development of these plaques

- Continued development of suitable animal models of atherosclerosis to allow study of basic mechanisms of the disease and to test new clinical methods of diagnosis and treatment

- Simple, safe, and inexpensive techniques for the early, noninvasive but reliable detection of asymptomatic atherosclerosis in humans

- An understanding of the basic mechanisms of arterial thrombosis that cause heart attack and stroke; in this effort, the heart and blood disease scientists are working together.

CORONARY HEART DISEASE

When atherosclerosis occurs in the coronary arteries it causes coronary heart disease. Although coronary atherosclerosis seems much the same as atherosclerosis in other arteries, it is presented separately because it represents a major public health problem. It kills over one-half million Americans each year and permanently or partially disables many more. It carries with it two catastrophic events--myocardial infarction and sudden death.

Myocardial infarction irreversibly damages heart muscle and, if extensive enough, may cause heart failure. Sudden death occurs because the electrical activity responsible for normal heart rhythm is disturbed, causing the heart to stop beating or to beat so chaotically that its pumping action is inefficient and inadequate. Obviously, a substantial saving of life and a marked improvement in health would be achieved if these catastrophes could be controlled.

Accomplishments

Substantial progress has been made in several areas that hold great promise for diminishing death and disability from coronary heart disease.

- A variety of methods for determining the size of a heart infarct have been developed and soon will have wide clinical application.
- Promising measures to limit infarct size and to decrease the threat of heart failure have come from laboratory investigations and will be tested soon in broad clinical trials.
- The population at risk of sudden death has been defined by several carefully conducted retrospective studies. Most of those individuals who died suddenly had severe coronary heart disease but no acute occlusion of a coronary artery; thus, electrical instability of the heart probably caused a fatal disturbance of cardiac rhythm.
- Surgical operations on coronary arteries to bypass obstructive lesions have been shown to relieve angina pectoris, one of the serious symptoms of coronary heart disease.

Requirements

Generally, the requirements for coronary heart disease are the same as for atherosclerosis: understanding basic mechanisms, biological expression of

risk factors, methods for detecting atherosclerotic plaques, and the problem of thrombosis. In addition, specific requirements for coronary heart disease include:

- Attainment of adequate knowledge of myocardial metabolism for the development of fail-safe methods to limit the size of cardiac infarcts.
- Identification of the factors that control the electrical activity of the heart and permit a normal cardiac rhythm in the face of severe, chronic coronary heart disease. This means continued study of electrophysiology and an improved understanding of the conduction system of the heart.
- Development of effective means of reducing the incidence of infarction and sudden death in our adult population with established coronary heart disease.
- Determination whether coronary artery surgery prolongs life or is useful only to relieve angina.

HYPERTENSION

High blood pressure is a serious and prevalent disease. There is now no question as to its magnitude in this country--about 15 percent of the adult population is afflicted. Hypertension causes a great many premature deaths and much disability from heart attacks and strokes. This threat can be much diminished, however, by the effective use of antihypertensive medications. This therapeutic benefit can be accomplished even though our current understanding of the disease is inadequate for prescribing curative measures. Although effective treatment is available, many physicians and patients do not appear to be committed to its proper and continuing use.

Accomplishments

Given the importance of good control of arterial blood pressure in hypertensive patients, the following accomplishments are especially significant:

- The success of the NHLI's Hypertension Education Program in motivating physicians to learn about hypertension and its treatment
- Increasingly effective therapy is being developed through improved understanding of the effects of drugs on the physiologic abnormalities that characterize hypertension.

Requirements

Hypertension can only be controlled, but not cured, at present. The adverse effects of hypertension on national health would be greatly decreased with the following:

- More intensive studies of the mechanisms influencing the contractile state of the smooth muscle that controls the caliber of small blood vessels and determines vascular resistance to blood flow. This information would allow development of improved therapies now.

- Increased motivational research to determine the best ways to help asymptomatic hypertensive patients seek treatment and to continue it for as long as necessary to control hypertension and prevent complications.

OTHER REQUIREMENTS FOR THE HEART AND VASCULAR DISEASES PROGRAM

In addition to atherosclerosis and hypertension, there are other aspects that the Council finds warrant consideration. These include other cardiovascular diseases and prevention, control, and education programs.

Other Cardiovascular Diseases

Although the Council has highlighted the accomplishments in the understanding of atherosclerosis and hypertension and the requirements in these areas for a strong, forward-moving program aimed at their control, this in no way diminishes the importance of other cardiovascular diseases. Much more information is needed about rheumatic heart disease, congenital heart disease, cardiomyopathies, and stroke.

- For RHEUMATIC HEART DISEASE, information is needed about patient compliance in long-term antibiotic therapy to control streptococcal throat infections and about the possibility of developing an antistreptococcal vaccine which would eliminate the need for such therapy.

- For CONGENITAL HEART DISEASE, the requirements involve learning its causes and initiating programs to improve the early recognition of infants with such heart lesions and to facilitate their prompt treatment.

- For CARDIOMYOPATHIES (diseases of the muscular tissue of the heart), the role of virus infections must be determined.

- For STROKE, information is needed about the genesis of the small aneurysms that are the major cause of hemorrhagic strokes as well as about atherosclerosis which is the basis for thrombotic strokes.

Prevention, Control, and Education

The National Heart, Blood Vessel, Lung, and Blood Act of 1972 called for programs of prevention, control, and education because the ability to improve health depends on physicians' and patients' recognition and acceptance of measures necessary to control illness and also to prevent it. These measures often involve a change in life style such as dietary modification, taking medication regularly and for long periods, and cessation of smoking. For such programs to be effective, they must be multifaceted, appropriate for different population groups, and carry a long-term commitment on the part of the NHLI. It is admittedly difficult to change life styles and much more information is needed about human motivation for the design of such prevention, control, and education programs. The Institute and the Council recognize the need for behavioral research in order that the mandate of the Act be implemented.

LUNG DISEASES

The Institute has moved rapidly and skillfully in establishing programs against lung diseases; expenditures in this field have reached the mandated 15 percent level. For 40 years the respiratory function of the lung was the only one studied intensively, whereas the majority of the new lung disease programs have been devoted to the discovery of basic knowledge about other functions of the lung which are important because they may be responsible for failure of respiratory function. Noteworthy progress has been made in many parts of the lung diseases program; two examples are especially interesting and will be summarized briefly here.

LUNG DISEASES OF INFANCY AND CHILDHOOD

Respiratory diseases in children are of numerous types, and they continue to represent a significant cause of morbidity and mortality. In responding to injuries to the respiratory tract, infants and children often exhibit airway obstruction. This is due, in part, to the peculiarities of the airways in children which may be more easily obstructed by a given injury.

Hyaline membrane disease (often called respiratory distress syndrome of the newborn) is a disorder characterized by immaturity of the lung with respect to its ability to manufacture and secrete agents that affect the mechanical properties of the lung. The disease is serious, and without specialized and prompt treatment, over 50 percent of the 50,000 babies afflicted per year die.

Accomplishments

Some of the most exciting advances in the application of new basic knowledge to the diagnosis and treatment of lung diseases have occurred in lung diseases of infancy. These advances are being transmitted rapidly to the hospitals and clinics of the nation.

- Basic biological and clinical research over the past ten years has provided a better understanding of respiratory distress syndrome of the newborn.

- This better understanding has led to the ability to detect the ailment before birth by sampling amniotic fluid which allows doctors to be prepared to initiate treatment promptly after birth.

- A simple new mode of treatment has been devised which involves the use of artificial pressure in the airways to keep them open and thus to maintain oxygenation of the blood. It must be emphasized that this treatment is best carried out in the special intensive care centers of large hospitals.

- A Military Accident and Safety Transport (MAST) Program has been initiated in three areas of the country so that newborns with respiratory distress syndrome can be transported rapidly to large centers for treatment.

- Educational programs have been initiated in several areas to acquaint physicians in small communities with the new advances in prenatal diagnosis, the detection of infants at risk, and transportation to the centers. These programs have been initiated with the support of the NHLI, the states, the Department of Defense, the American Academy of Pediatrics, and the American Lung Association.

Requirements

Important needs remain in the area of lung diseases of childhood:

- Carefully conducted trials of new modes of treatment are essential. A study of artificially increased airway pressure and its therapeutic effectiveness in respiratory distress syndrome of the newborn has been initiated by the NHLI. It is expected that early detection of the disease, along with this new therapy, may yield a drastic reduction in mortality in these infants.

- There is the possibility that we may be able to prevent many cases of respiratory distress syndrome of the newborn by prenatal detection of the disease and drug treatment of the mother to accelerate maturation of the infant's lungs. This possibility arose out of clinical observations which have now been tested in many laboratories. A clinical trial of this new therapeutic approach will be started, supported by the NHLI, the National Institute of Child Health and Human Development (NICHD), and the World Health Organization (WHO). Thus, prevention as well as treatment of the disease may soon be possible.

- Although some advances have been made, the conquest of other lung diseases in children is not progressing as well as in respiratory distress syndrome of the newborn. The NHLI's activities in certain areas should be continued and expanded: basic studies of the biology of the lung and epidemiology of childhood lung diseases as they relate to chronic adult disease, the development of new testing methods which can be used in children, and clinical studies of cystic fibrosis and bronchiolitis in children.

Several voluntary health agencies have concentrated their efforts on programs emphasizing the importance of curing or alleviating pediatric pulmonary diseases. Conferences have been held concerning the serious need for manpower in this area, for development of pulmonary function testing for children, and for increased recognition and treatment of exercise-induced asthma. These efforts, however, are only the beginning. Suggestions for future work parallel, in general, those made for adult lung diseases, but they also specifically include implementation of chronic therapy for asthmatics, antismoking campaigns among children and adolescents, and increased testing for viral agents in childhood infectious diseases.

RESPIRATORY FAILURE AND RESPIRATORY ASSISTANCE

Respiratory failure occurs in an ever increasing number of Americans as a result of the alarming increase in chronic respiratory disease, emphysema, and bronchitis. Treatment of many respiratory diseases is addressed primarily to the alleviation of symptoms rather than to the underlying cause. Although this is an important approach, it is a limited one and a reflection of our serious lack of information concerning the basic causes of lung disorders.

Acute respiratory failure strikes previously healthy individuals as well as patients with emphysema and bronchitis. When respiratory failure occurs, the mortality rate is 40 percent, resulting in approximately 60,000 deaths per year.

Accomplishments

It has been demonstrated that mortality from respiratory failure can be reduced by half through application of the principles of respiratory physiology in modern intensive care units. Through basic research programs in respiratory physiology and the biology of lung injury and healing, the NHLI and voluntary agency programs are advancing the scientific basis of patient care.

- Contract programs have been initiated to develop educational programs for practicing physicians and health professionals in community hospitals.

- In the field of respiratory failure and assistance, the most exciting area is the development of a safe artificial lung machine capable of keeping the patient alive while the severely injured lung is given a chance to heal. The NHLI has wisely undertaken an evaluation of the effectiveness of the artificial lung before this very expensive therapy is introduced widely. The Institute is perhaps in a unique position to test such expensive methods quickly and scientifically.

Requirements

NHLI-sponsored programs are already underway to meet a number of important needs:

- The cost of some new therapeutic approaches is extremely high. For example, the cost of inhalation therapy, which is a widely used method of treatment, approaches $2 billion per year and accounts for some of the increased hospital costs in the nation. Ways must be found to improve the efficacy of this therapy while decreasing its cost.

- Well designed programs should be launched for the development and evaluation of techniques for the early detection and subsequent monitoring of respiratory failure. There is a nationwide shortage of trained physicians and technicians who are able to utilize and administer the new sophisticated therapies. Long-term clinical evaluations of developing therapeutic approaches, including those involving new instruments and devices, will be necessary.

OTHER REQUIREMENTS OF THE LUNG DISEASES PROGRAM

With respect to the programmatic needs, the Council wishes to cite three principal areas.

Manpower Development

Several panels and committees have documented the serious shortage of manpower in all professional activities in lung diseases: physicians to practice adult and pediatric chest medicine; medical school faculty to teach medical students, interns, and residents; and scientists to engage in basic and clinical research on pulmonary and respiratory problems. Although the NHLI has developed pilot programs in all these areas, there will be a significant time lag before an adequate manpower supply can be developed.

Of particular significance is the recently established National Pulmonary Faculty Training Program which is designed specifically to relieve the critical shortage of faculty in the pulmonary divisions of medical schools in this country. To ensure that within a five-year period every medical school can have at least the nucleus of a strong pulmonary faculty, the following new program has been proposed by the Council and the Institute. Acknowledged pulmonary centers will accept young physicians and basic scientists for long-term training; hopefully, these young biomedical scientists will return to full-time academic positions in their schools. This program involves a partnership agreement among the NHLI, the medical school in need of trained faculty, the training center, and the young faculty member who requires additional training. Early initiation of this program is not only desirable but entirely consonant with the mission of the Institute.

Basic Biologic Lung Research

This continues to be an acute area of need because, until recently, research in this field has lagged. Almost every area of basic pulmonary research requires added emphasis and support. Despite this need, as already noted, "payoffs" are beginning in such areas as asthma, adult and infant respiratory distress syndrome, and respiratory failure.

Prevention, Control, and Education

The Council and the Institute have recognized the need for greater effort in the education of the medical and lay communities with respect to lung diseases for the better control of preventable lung disease and for the rapid dissemination of information derived from the explosion of basic biologic information about the lung. The application of the NHLI's resources for control and education has occurred as the Lung Division's funds have grown six-fold from $7 million in 1970 to $43 million in 1974. Through seminars, workshops, and programs at both the

local and national level, the interests, concerns, and abilities of the research community have focused on public education and the control problem. The new control programs in pediatric respiratory distress and occupational lung diseases are examples. The recent National Research and Demonstration Center competition has placed great emphasis on the control and educational aspects of cardiovascular, blood, and lung diseases. One lung center will be funded this year with a major emphasis on education and demonstration.

The Institute has cooperated actively with many non-governmental agencies such as the American Thoracic Society, the American Lung Association, and the American College of Chest Physicians to improve the education of both the medical profession and the lay public. Much has been done to encourage the establishment of lay and paramedical training programs for respiratory therapists, the establishment of centers for acute respiratory disease, the application of the MAST program to civilian patient transport, and the development of public awareness to the hazards of smoking. National efforts directed against smoking seem to have been particularly effective judging by the large number of Federal, state, and local laws introduced to segregate smokers in public places or to prohibit it entirely.

Obviously much more needs to be done, especially in the control of preventable chronic lung disease, motivation to stop smoking, treatment of acute respiratory disease, and mobilization of community resources for education and control. The involvement of other Federal agencies should be pursued vigorously. Improved and better coordinated local campaigns should be waged against smoking, occupational disease, etc. Improved transport and more clinical centers for care of infants with respiratory distress syndrome should be established. Research in the best community education methods and motivational programs is urgently needed.

BLOOD DISEASES AND BLOOD RESOURCES

The Blood Diseases and Blood Resources Program is vitally important in its own right and is intimately related to the Institute's responsibilities in both cardiovascular and pulmonary diseases. Blood plays a key role in such diverse functions as coagulation, oxygen transport, immunity, protein balance, circulatory control, and it is often implicated in disorders of the heart and lungs. The Institute is seeking to be responsive to the Program described in the legislative Act of 1972 which specified provision for " . . . studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, and distribution of it and its products."

THROMBOSIS

Thrombosis (clotting of the blood within the blood vessels) contributes significantly to the high morbidity and mortality associated with diseases of the heart and blood vessels. Arterial thrombosis is implicated in heart attacks and strokes while venous thrombosis can result in pulmonary embolism. Further, clotting of blood on artificial surfaces seriously limits the development of life support devices such as the artificial heart or lung.

Accomplishments

Recent developments suggest that an understanding of thrombosis and its control will soon be improved.

- Platelets (small discs found in the blood that are associated with clotting) have been found to be important in all types of thrombosis; their clumping (aggregation) often is one of the earliest and most reversible steps leading to thrombosis.
- Clinical research has resulted in the more sophisticated use of anticoagulants with particular emphasis on heparin and the use of compounds that inhibit the aggregation of blood platelets.
- Radioisotope and other methods are being developed to detect, measure, and localize thrombosis in the circulatory system.
- Progress is being made in the understanding of interactions between artificial surfaces and blood, and in the development of materials that do not promote clotting and can be used for circulatory and pulmonary support systems.

Requirements

Progress in the thrombosis area requires an understanding of the physiology of the blood platelet and chemical interactions of coagulation factors. Such basic research must be continued and expanded. Promising areas include:

- New research into the interaction of blood components with synthetic and natural nonthrombogenic materials
- Development of suitable animal models for thrombosis research
- Epidemiologic studies on the relationship between diet, platelet function, and the incidence of thrombosis.

HEMOPHILIA AND HEMORRHAGIC DISORDERS

The hemophilias are a group of hereditary disorders in which the patient's blood clotting mechanism is deficient. This causes uncontrolled bleeding when the patient is injured or undergoing surgery unless appropriate clotting factors are supplied promptly. Treatment, at enormous cost, must be continued throughout the patient's life to prevent crippling or death, and it places the largest single demand on the nation's blood supply. Therefore, while the number of hemophiliacs is relatively small compared to individuals with other diseases, their treatment constitutes a major national problem.

Accomplishments

The continuing NHLI-supported programs do offer promise for lessening this problem.

- Studies on the use of animal sources of Factor VIII (the blood factor with antihemophilic activity) are proceeding to the point of clinical trials; this may be a lifesaving development for some hemophiliacs.

- Clinical research has been directed toward improved methods for preparing Factor VIII.

Requirements

Clearly, if substantial progress is to be made, new information and new methods of treatment are necessary.

- A simple substitute for plasma fractions or purified Factor VIII should be developed.

- Basic research on the molecular characteristics of compounds that have Factor VIII activity must be expanded and intensified to provide for development of the substitutes for natural Factor VIII.

- Methods should be developed for the comprehensive care of patients with hemophilia in areas where only limited medical facilities exist.

- Research and development to improve the efficiency and economy of producing antihemophilic factors from human and animal sources need support.

- Methods to identify persons who are "carriers" of hemophilia should be improved.

SICKLE CELL ANEMIA AND RELATED INHERITED DISORDERS

The Sickle Cell Disease Program, initiated in 1971 by the President and confirmed by passage of the Sickle Cell Anemia Control Act in May 1972, is being carried out through the NHLI and through agreement with the Health Services Administration (HSA). The latter is responsible for 26 clinics for developing screening and counseling techniques for education of the public at large and those affected directly.

Accomplishments

Basic research has identified the importance of the structure of the red blood cell wall in the sickling phenomenon and several agents have been found which alter the sickling process.

- Encouraging preliminary results involving the use of sodium cyanate may lead to controlled clinical trials if toxicological studies permit.

- It has been demonstrated that the defect in Cooley's anemia (inherited hemoglobin abnormality) is in the cellular material that carries the genetic code message, i.e., messenger RNA.

Requirements

Although a start has been made, modern and reliable testing facilities and procedures for sickle cell disease and trait must be made more widely available.

- New tests for detection of sickle cell anemia and sickle cell trait in newborn infants need further development.

- Agents that reliably alter the sickling process are needed.

BLOOD RESOURCES: A SPECIAL NEED

The Council is concerned that progress has not been more rapid, particularly with regard to the best use of blood resources. Areas where action is appropriate were identified in the June 30, 1972, Institute report[3] on this subject. There is still a need to determine the extent to which serious problems may exist in the availability of blood and its derivatives to patients.

- A nationwide study should be undertaken to define how well the present system provides needed blood and blood derivatives to the patient. If deficiencies exist, the reasons for them should be identified.

Accomplishments

In spite of the Council's concern about the availability of blood, it recognizes that progress has been made.

- The Department of Health, Education, and Welfare has asked the private blood banking sector to create the American Blood Commission. Hopefully, this will lead to the implementation of the National Blood Policy.

- A study has been completed which sets forth a national cost-finding methodology adaptable to the blood banking community which can form the basis for establishing a uniform, rational pricing policy.

- Advances in the detection of hepatitis virus in blood and the possibility of developing vaccines are two promising leads in the control of post-transfusion hepatitis.

- Progress has been made in methods for blood storage and more efficient separation of blood into useful components.

Requirements

Blood transfusion is really the transplantation of a biological tissue. Many of the problems in blood transfusion are common to the transplantation of other tissues and organs, and need to be addressed in a common framework. Particular needs are:

- Reliable and economical methods for storing blood by freezing

- Prevention of development of refractoriness to platelet transfusions, and the supportive care of patients whose bone marrow is malfunctioning

- Development of new synthetic materials highly permeable to oxygen to improve heart-lung machines.

[3] NHLI's Blood Resource Studies. Summary Report. DHEW Publication No. (NIH) 73-416. June 30, 1972.

BLOOD RESOURCES: MANPOWER NEEDS

Accurate and timely data on manpower development needs and resources are necessary, especially in this period when both the Federal goals in manpower development and the mechanisms to achieve the goals are under consideration.

Blood banking presents a special problem. A recent report of a panel of the National Research Council found a serious shortage of well-trained professionals and pointed out the need for their development in blood banking and transfusion therapy. The panel called for a well-designed manpower development program with a realistic means of financial support.

In view of the national commitment to improve the nation's handling and distribution of blood, the Council recommends that five or six institutions be awarded grants on a competitive basis for the purpose of establishing model training programs in blood banking and transfusion therapy.

IV

STATUS OF IMPLEMENTATION OF THE NATIONAL PROGRAM

A variety of facilities and resources and of mechanisms is essential if the objectives of the National Program to control heart, blood vessel, lung, and blood diseases are to be achieved.

RESOURCES AND MECHANISMS

MANPOWER DEVELOPMENT

The abrupt phaseout of NIH research fellowships and traineeships in 1973 created serious concern in the scientific and medical communities because it produced a net loss to the nation's research manpower pool that it could ill afford. The loss was equivalent to the number of scientists who would have begun research careers during that entire year. Added to this, the disillusionment of young people at the predoctoral level who had hoped to enter research training is apparent in medical schools and research institutions throughout the country and is a direct consequence of the uncertainties created by the abrupt changes. The extent of these changes is shown in Figure 1.

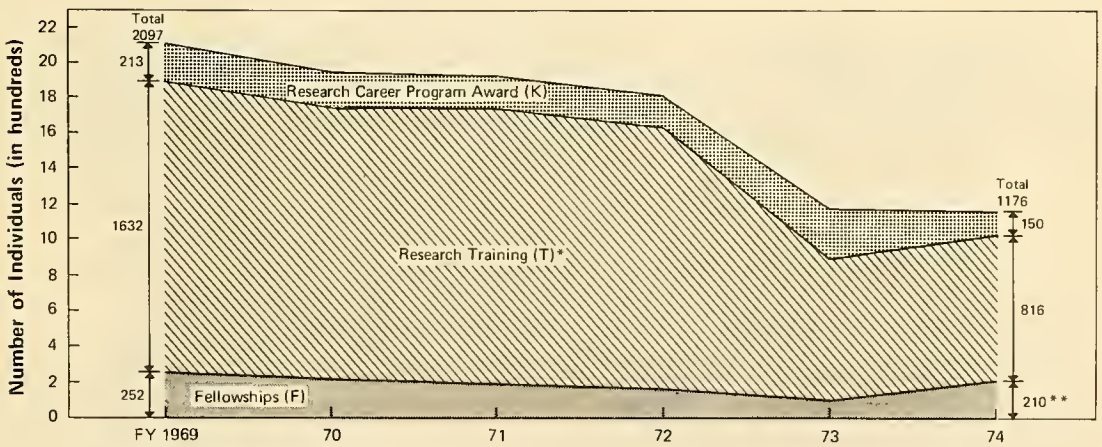

Figure 1. Number of Individuals Supported by NHLI Training Programs for Fiscal Years 1969-74

The National Heart and Lung Advisory Council, as it indicated in its First Annual Report,* was unwilling to believe that the intent was to *decrease* research on diseases of the heart, blood vessels, lungs, and blood in the same year that both the Congress and the Administration expressed their intention to *increase* the attack against these same diseases. Despite the fact that training programs were restored temporarily through the release of impounded funds and then through the creation of a "Manpower Development Fellowship Program" (the "Weinberger Program"), the curtailment of training awards restricted sharply the training continuity of young scientists.

The National Research Service Award Act of 1974 (Public Law 93-348)

The Council views with favor the enactment of this legislation to restore individual fellowships and institutional manpower development programs. It urges broad interpretation of the provisions of the Act dealing with biomedical and behavioral research training, and flexibility in the administration of the new program as well as in the training areas to be supported, and in the enforcement of payback provisions. Further, the Council hopes that Federal support for research training will continue to be viewed as an essential element in meeting the health goals of the nation, and that this support will be protected from excessive administrative restrictions.

The Act of 1974, when implemented, will help, but it has many potential difficulties and shortcomings. Training is to be supported only in areas where there is a documented shortage, and the shortage areas must be confirmed by the National Academy of Sciences. However, the results of a complete, in-depth study by the Academy probably cannot be available before March 31, 1976.

If the national needs are to be met, manpower development opportunities in the following NHLI research areas are essential:

- CARDIOVASCULAR DISEASES. Estimates by the NHLI and the American Heart Association, along with a study by the American College of Cardiology, indicate that a minimum of 600 new cardiovascular research trainees must begin training in 1975 if ongoing heart research programs are to be maintained at current levels. This minimum figure should be revised upward annually as additional scientists are needed to follow through on recent breakthroughs in atherosclerosis, coronary heart disease, and hypertension research, as well as to provide scientists for areas currently identified as being short of manpower, such as epidemiology, behavioral science, population genetics, biostatistics, and nutrition. The Council recommends, therefore, that at least 600 training positions at the predoctoral and postdoctoral levels be added to the Institute's extramural manpower development programs as soon as possible.

*See footnote 2, page 4.

- LUNG DISEASES. It is estimated that within the next two to three years, approximately 550 well-trained individuals will be required to fill vacancies on the staffs of medical schools and research institutions engaged in lung research. There is an increasing need for people trained in basic sciences, including biochemistry, cell biology, immunology, and bioengineering, to capitalize on recent discoveries. After consideration of the Institute's current programs for developing research manpower in the pulmonary field and after reviewing the detailed manpower data available from the American Thoracic Society, the American College of Chest Physicians, and the Subspecialty Board on Pulmonary Diseases of the American Board of Internal Medicine, the Council agrees that there is a need to support an additional 300 trainees at the predoctoral and postdoctoral levels in the field of lung research as soon as possible.

- BLOOD DISEASES AND RESOURCES. The NHLI has collected manpower data from a variety of independent sources. At least 125 vacancies currently exist for hematologists (blood specialists) in our medical schools, primarily for positions in research and teaching. Approximately 300 trainees in the blood area should be in training now to meet the needs projected by the programs mandated by the 1972 Act.

The Council wishes to support the concept that manpower development in all relevant disciplines should be continued at some modest, appropriate level even while shortage areas are emphasized. The importance of maintaining a balance of trained research manpower in both the clinical sciences and the basic biomedical sciences cannot be overemphasized. An abundance of foresight and wisdom will be required to assess correctly the nation's biomedical manpower needs as an ongoing process so that today's apparent surpluses in particular disciplines do not become the shortages of the future.

The Institute expects that $20 million will be available for manpower development in FY 1975. The Council believes that this amount is inadequate and urges that the allocation be increased to $32 million in FY 1976 to accommodate new programs and new areas of research and to adjust to the deficiencies created by the phaseout of 1973.

Special Research Fellowships

For years, many of the Institutes of the NIH supported a program of special research fellowships. These were often used for more advanced scientists to obtain special experience or to capitalize on special research opportunities in institutions other than those in which they were employed. This program, although never large, made it possible for many mature scientists to enhance their skills, add to their knowledge, acquire new techniques and, in so doing, to enhance their ability to pursue fundamental areas of research in different directions or in greater depth. This program clearly has been in the national interest and the Council urges that the Special Research Fellowship program be reinstituted.

PROFESSORIAL RESEARCH GROUPS

A model for this program presently exists in other countries where it has proved to be very successful. The Council wishes to reaffirm its conviction that the program described in the Council's initial report* be initiated, perhaps in stages, so that the benefits and effectiveness can be evaluated. It would provide support for a small research unit consisting of several talented and imaginative men and women who wish to devote their careers to research in diseases of the heart, blood vessels, lungs, and blood. Salary and research support for these groups should come from the Federal Government as part of the National Program.

RESEARCH PROFESSORSHIPS

The Council recommended the establishment of Research Professorships in its initial report.* The proposal was submitted to the Department of Health, Education, and Welfare which identified problems in its implementation. Recognizing that there is a difference of opinion on the philosophy of the program, the Council urges that it be initiated on a pilot basis so that its effectiveness can be properly assessed.

RESEARCH GRANTS

The Council expresses its unanimous and unequivocal support of the investigator-initiated research grant which represents the cornerstone of the NHLI programs as well as all research programs of the NIH. It is gratifying to note that the Office of the Director, NIH, shares this view. In its strong advocacy of this program, the Council notes that, over a period of time, it has proved ideally suited to fostering individual creativity of the highest order leading to a continuing flow of important biomedical contributions. However, inflation has increased the cost of research, and the percentage of approved research grant applications funded has decreased. Including new, renewal, and supplemental research grant applications, the award rate for approved applications has decreased from about 84 percent in FY 1964 to 51 percent in FY 1974.

CONTRACT SUPPORTED RESEARCH AND DEVELOPMENT

The Council recognizes that dependence on investigator-initiated programs may result in a failure to emphasize certain scientific areas of importance to national health needs and acknowledges the value of contract-supported and targeted research in eliminating such deficiencies. However, it feels strongly that funds for contract research should not displace those for investigator-initiated research. The Council believes that it should be fully informed about contract programs, particularly in early planning phases to fulfill its responsibility in providing advice to the Institute. It endorses the peer group review

*See footnote 1, page 4.

policy of the Institute, utilizing primarily non-government consultants to evaluate the merits of contract proposals and is favorably impressed with the Institute's management of contracting procedures and processes.

- The Council expresses a continued desire to be involved in the philosophy and planning of research programs to be supported by the contract mechanism.

OTHER CURRENT SUPPORT MECHANISMS

The Council is satisfied with the progress of other support mechanisms of the Institute such as Program Project Grants, Research Career Development Awards, the Pulmonary Academic Award, the Young Investigator Pulmonary Research Grant, the High Blood Pressure Education Research Program, and the Specialized Centers of Research (SCORs). The Council wishes to express its satisfaction with the dedicated staff work that has gone into the continuing management of these programs.

ANIMAL MODELS FOR THE STUDY OF HUMAN DISEASES

Many areas of research in heart, vascular, lung, and blood diseases would be greatly facilitated if better animal models were available.

A model of spontaneously occurring atherosclerosis would allow study of factors that are not now possible with the models available. The animal models currently used require highly artificial measures for their development, and their relationship to human arterial disease is uncertain.

Animals usually do not suffer from venous and arterial thrombosis as man does. However, there is reason to believe that animal models of vascular thrombosis could be developed. Such models certainly would increase our understanding of pulmonary embolism, myocardial infarction, and thrombotic strokes.

Disorders of fat metabolism occur frequently and seem causally related to premature atherosclerosis. Development of animal models mimicking these human disorders would allow study of the genetic determinants of the disorders and how they predispose to premature vascular disease.

A particular need for the entire research community is the increased availability of non-human primates. The primate often provides a much better model for a wide variety of human afflictions than do non-primate species. Several reasonably good primate models are available for atherosclerosis, hypertension, and hepatitis research, but better ones are needed for the diseases that have been mentioned, as well as for stroke, chronic emphysema, and other lung diseases.

- The Council believes that additional efforts should be made by the Institute to increase the supply of primates available for research purposes.

THE NATIONAL RESEARCH AND DEMONSTRATION CENTERS

The Act of 1972 authorized the Director of the NHLI to establish as many as 30 National Research and Demonstration Centers for heart, blood vessel, blood diseases, and diseases of the lung. The Council continues to be supportive of this new program, but it is clear that unless financial resources are made available, the creation of additional Centers will not be possible.

- The Council, therefore, recommends that additional funds for National Research and Demonstration Centers be identified specifically in the budget.

- The Council takes the same position now that it did in its First Annual Report* and recommends that only a few such Centers be funded initially and that sufficient time be permitted for careful review and evaluation of the strengths and weaknesses of the program before funds for the full number of authorized Centers are appropriated.

CONSTRUCTION

The Council continues to place a very high priority on the construction of research facilities. The Act of 1972 gave the NHLI authority to support construction, but no appropriation has been made for this purpose. Since existing facilities in medical centers and research institutions are heavily utilized, it is doubtful that many of the new programs, including the National Research and Demonstration Centers, can be developed effectively. Furthermore, as medical schools are encouraged to train more physicians for practice, the facilities for research activities are being encroached upon. Funding for additional research facilities is needed in many centers if research efforts are to be sustained and intensified.

The Council believes that funds for construction should be appropriated as a line item for the Institute, and they should not be limited to National Research and Demonstration Centers but granted for construction or modernization of any of the facilities essential to the success of the overall Program of the Institute. The Council urges that institutions not be required to provide matching funds for construction. Funds should be available to scientists and institutions able to make the greatest contributions to the National Program by virtue of having additional facilities; advantage should not be given to those whose potential contribution may be less, but who have access to non-Federal funds for matching purposes. Federal funding for construction with little or no matching requirement permits research institutions with limited funds to apply. This would further the national interest by permitting research groups to develop in more institutions and would reduce the possibility of unwarranted concentration of gifted scientists in the more affluent institutions.

*See footnote 2, page 4.

MINORITY AND OTHER PARTICIPATION IN THE NATIONAL PROGRAM

The Council, in its First Annual Report,* encouraged the development of research programs in institutions where, for a variety of reasons, this capability is deficient or nonexistent. The Council feels that the NHLI is in a unique position to provide influence in this particular area, both through support of research and through the development of programs bringing minority and other scientists from these institutions into the mainstream of biomedical research.

Two ad hoc working committees of the Council were convened in March 1974 and will formulate recommendations to the Council for transmission to the Directors of the NHLI and the NIH. One of these working groups is to address itself principally to non-minority institutions that are not now included in the NHLI's programs but which are involved in the teaching of biomedical sciences. The other specifically addresses the problems of minorities both as individuals and as institutions. Considerable importance will be placed on obtaining input from minorities in order to be sensitive to their needs.

PREVENTION, CONTROL, AND EDUCATION

Section 414 of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 directed the Institute to establish prevention, control, and education programs related to heart, blood vessel, lung, and blood diseases. Programs are being developed now that seek the efficient and immediate translation of basic research results into broad and specific systems and programs of disease prevention, control, and education for the lay and professional communities. Such new programs will develop interfaces and cooperative arrangements with appropriate private, state and Federal agencies, organizations, and institutions as they may apply to disease entities within the purview of the NHLI. A major effort will be the formulation of suitable programs for encouraging the public to develop habits that may be of benefit in preventing the development or progression of heart, blood vessel, lung, and blood diseases. Initial planning and implementation of several programs are already underway and include, but are not limited to, the following: disease-oriented, regional and school health programs; programs for community health education, and continuing medical education.

Education and the use of paraprofessionals in community efforts designed to control and prevent disease are to be stimulated; the concept of health delivery teams, which includes patient education, is gaining rapidly in acceptance. Although categorical disease approaches to prevention, control, and education will be used, the Institute will coordinate and give highest priority to those programs that can serve as models for other diseases as well.

*See footnote 2, page 4.

As resources become available, the Institute plans to provide funding for local and regional demonstration programs which embrace the above principles. These programs must involve the several components of the health care system in a given geographical area, although they may be based primarily in the medical schools or major medical centers. While it is not intended to fund health care delivery per se, it may be necessary to provide support for the manpower necessary for coordination, for educational opportunities, and for the preparation and dissemination of educational or informational materials. These programs should receive support on the basis of assessment of merit in national competition.

Thus far for FY 1975 and FY 1976, hypertension and sickle cell disease are the highest priority categorical areas and modest funds currently are available for educational programs. In addition, new efforts will be directed to cardiac rehabilitation (patient education), nutrition and coronary artery disease risk factors, early diagnosis of respiratory distress syndrome of the newborn (including prenatal diagnosis), smoking as a risk factor, improved approaches to blood component therapy, and public education regarding the need for an all volunteer national blood donation system.

ADMINISTRATIVE ARRANGEMENTS

INTERAGENCY RELATIONSHIPS

The Act of 1972 (Section 416) required the Secretary to establish an Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources, and designated the Director of the NHLI as chairman. The Act further required the National Program to provide for coordination of the Institute's programs and related programs of other agencies. The Interagency Technical Committee has been established and consists of sixteen members: eight from the Department of Health, Education, and Welfare, and eight from other Federal agencies. It has been an effective instrument for interchange of information about ongoing research and for securing data about the scope of heart, blood vessel, lung, and blood disease and blood resource activities throughout the government. The Council anticipates that the benefits of collaboration and information exchange among the agencies of the Committee will continue to be productive.

The Institute staff also participates in a large network of committee-like activities, both formal and informal. In some of these, the NHLI is the lead agency while in others it is a member-participant. It is estimated that these interagency relationships occupy approximately 1,000 man-days of staff time per year.

It is obvious that the mechanism of interagency relationships is highly developed as a means of coordination, collaboration, and planning, and in information exchange under the NHLI's National Program. Among these relationships are the activities in information exchange that are now developing at the international level.

- The Council believes that the interagency relationships defined in the legislation of 1972 and the other interagency relationships should be continued and refined, but it also believes that additional staff members are needed to take full advantage of the relationships that have been developed.

STAFFING

After careful study, the Council is convinced that the Institute has insufficient staff to fulfill its mandate effectively since the programs of the Institute have grown in number and variety. Each of the three categorical Divisions--the Division of Heart and Vascular Diseases, the Division of Lung Diseases, and the Division of Blood Diseases and Resources--has responsibility for major new programs which require increased staff participation. The Division of Extramural Affairs has responsibility for reviewing all applications for National Research and Demonstration Centers and a wide variety of other new and special programs. All of the Divisions are attempting to cope with growth in the contract mechanism for the support of research. A variety of Specialized Centers of Research has been developed, and there are a number of other specialized programs such as the Pulmonary Academic Award and the Young Investigator Pulmonary Research Grant, as previously mentioned. In the Council's view, it is clear that the growth in staff has not been commensurate with the growth in programs.

The new emphasis on lung disease and blood disorder programs, coupled with constraints upon the addition of new personnel, has placed the staff under considerable pressure. Between FY 1970 and FY 1974, the NHLI fiscal obligations increased by 78 percent, but employment increased only 23 percent. The Council has been impressed with the responsiveness of the staff in meeting the challenges of new and expanded programs, and in functioning under the difficult and demanding pressures which have been brought about by these major programs. The continued shortage of staff resources in the face of expanding programs is now a serious handicap in maintaining an efficient, high quality operation.

- To provide for adequate staffing of the expanded programs, the Council urges that the NHLI staff be increased to approximately 800 permanent, full-time positions.

SPACE

The Council is especially concerned about the space arrangements in which the staff members of the Institute must operate; they are now dispersed in three separate locations that are miles apart. It is difficult to understand how a limited staff can be expected to work efficiently in the face of increasing program requirements when located in such widely separated locations.

- The Council urges that the NIH arrange for consolidation of space in an appropriate location.

NHLI BUDGET

The Council believes that the determination of the budget for the NHLI should be made in the public arena as has been done in the past. It wishes to reaffirm its position on this subject as stated in the First Annual Report:

> "Congressional Determination of the Budget of the National Heart and Lung Institute. The Council believes that the programs of the National Heart and Lung Institute are so important to the welfare of the American people that the major decisions concerning these programs should be in the public arena. Specifically, the Council recommends that the present system by which the Congress now establishes separate line items in the Federal budget for the National Heart and Lung Institute be continued to assure public and congressional access to both planning and review of the programs of the Institute."*

The NHLI annual budget for FY 1974-80, as presented in Table 2, shows the amounts allocated, appropriated, or recommended for various program activities.

In developing its budget recommendations, the Council has been impressed by several major discrepancies between congressional authorizations and the actual implementation of the Act. The following are major areas of fiscal concern since each reflects an area of need discussed by the Council elsewhere in this report:

- The number of research grant applications approved but not funded has been increasing. The percentage of approved applications that have been awarded has decreased from about 84 percent in FY 1967 to 51 percent in FY 1974 due to the limitation of research grant funds available. The Council hopes that sufficient funds will be appropriated by the Congress so that important needs of the National Program may be met.

*See footnote 2, page 4.

- A reduction in manpower development funds and uncertainties about programs occurred also (see Figure 1), so that approximately 900 fewer scientists were being trained in FY 1974 than in FY 1969 in the cardiovascular, blood, and lung fields.

- There was an increase of almost 70 percent in total NIH research support between FY 1967 and FY 1974. The percentage allocated to the NHLI remained virtually constant in this period, as shown in Table 3, despite the intent of Congress to increase cardiovascular, lung, and blood research. At the same time, the percentage of funds allocated to most other Institutes decreased sharply. The Council strongly recommends that balance be restored to these programs primarily by increasing support to other Institutes where important biomedical research has suffered. This is especially true of the National Institute of General Medical Sciences (NIGMS) which supports many biomedical research programs in sciences basic to continued advances in cardiovascular, lung, and blood research.

- In the annual budget recommendations prepared for the First Annual Report* and for this report (see Table 2), the Council has tried to estimate as realistically as possible the funds which are required to implement the National Program. Table 1 indicates clearly the differences between the funds authorized by the Congress and those appropriated. The lack of construction funds does not remove the necessity for them in FY 1976 and actually increases the problems as costs escalate. Other examples could be cited. The recommended budget reflects these and other considerations for the sound National Program outlined in Chapter III.

Table 3. Percentage Distribution of NIH Research Support for Fiscal Years 1967, 1971, and 1974

Institute	FY 1967	FY 1971	FY 1974
National Heart and Lung Institute	15%	15%	17%
National Cancer Institute	16	19	30
All Other Institutes/Divisions	69	66	53
TOTAL	100%	100%	100%

*See footnote 2, page 4.

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